

## **II. Remarks**

### **A. Status of the Claims**

Claims 1, 4, 11 and 57 have been amended without prejudice or admission. Applicants submit that support for the amendments can be found, e.g., in original claims 12 and 13; and in paragraphs [0024] and [0025] of the original specification.

Claims 12 and 13 have been cancelled without prejudice or admission.

Claims 1-11, 14, 16, 17 and 53-60 are pending, with claims 8 and 9 withdrawn from consideration.

Claims 1-7, 10, 11, 14, 16, 17 and 53-60 are encompassed by the elected invention and the elected species.

It is respectfully submitted that no new matter has been added by virtue of the present amendments.

### **B. Claim Rejections- 35 U.S.C. § 103**

#### **1. Claims 1-3, 5-7, 10-14, 16, 17, 53-55, 57 and 60**

Claims 1-3, 5-7, 10-14, 16, 17, 53-55, 57 and 60 have been rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,639,476 ("Oshlack") in view of U.S. Patent No. 6,136,345 ("Grimmett"), further in view of U.S. Publication 2003/0191147 ("Sherman"). The Examiner stated that Oshlack differs from the instant application in that it does not teach a coating made of hydrophobic material over the anionic polymer coating," and has relied on Grimmett to cure this

deficiency.

The rejection is respectfully traversed.

Independent claims 1 and 57 have been amended to recite that the claimed formulations comprise a plurality of coated substrates, each substrate overcoated with two layers- a diffusion barrier coating of an anionic polymer and a coating of a hydrophobic material over the diffusion barrier coating.

Applicants respectfully submit that Grimmatt (the reference relied upon by the Examiner for the teaching of a coating of hydrophobic material over the anionic polymer coating) is purportedly directed to a tablet formulation comprising a single core, and states that “coating of a single relatively large core in the tablet of the invention with a release-retarding coating requires less coating material than is required to coat a larger number of smaller granules, and can therefore lead to a relatively low tablet weight.” Column 1, lines 49-53. Applicants therefore submit that Grimmatt would not have suggested to a skilled person to coat a plurality of substrates with two coatings as recited in claims 1 and 57, as it would have suggested a single core formulation. Accordingly, Applicants submit that Grimmatt does not cure the deficiency of Oshlack, and that the combination of the cited references does not render claims 1 and 57 and their dependent claims obvious.

Applicants further submit that the skilled person would have no reason to combine the references in the manner suggested by the Examiner, as there is nothing in the cited references to suggest that a formulation comprise a plurality of coated substrates, each substrate overcoated with two layers as recited in claims 1 and 57, is desirable or advantageous.

Withdrawal of the rejection is therefore respectfully requested.

**2. Claims 1, 4, 58 and 59**

Claims 1, 4, 58 and 59 were rejected under 35 U.S.C. § 103(a) over U.S. Patent No. 5,639,476 (“Oshlack”) in view of U.S. Patent No. 6,136,345 (“Grimmett”), further in view of U.S. Publication 2003/0191147 (“Sherman”), further in view of WO 01/58447 (“Oshlack II”).

The rejection is respectfully traversed.

Claims 1 and 57 have been amended to recite that the claimed formulations comprise a plurality of coated substrates, each substrate overcoated with two layers- a diffusion barrier coating of an anionic polymer and a coating of a hydrophobic material coated over the diffusion barrier coating.

Applicants respectfully submit that the combination of the cited references does not teach or suggest a formulation comprising a plurality of coated substrates as recited in claims 1 and 57, for the reasons set forth above.


Applicants further submit that the skilled person would have no reason to combine the references in the manner suggested by the Examiner, as there is nothing in the cited references to suggest that a formulation comprise a plurality of coated substrates, each substrate overcoated with two layers as recited in claims 1 and 57, is desirable or advantageous.

Withdrawal of the rejection is respectfully requested.

### **III. CONCLUSION**

An early and favorable action on the merits is earnestly solicited. The Examiner is respectfully requested to contact the undersigned by telephone in the event that a telephonic interview will advance the prosecution of the present application.

Respectfully submitted,  
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